Citation:

Shah M, Adams-Huet B, Bantle JP, Henry RR, Griver KA, Raatz SK, Brinkley LJ, Reaven GM, Garg A. Effect of a high-carbohydrate versus a high--cis-monounsaturated fat diet on blood pressure in patients with type 2 diabetes. *Diabetes Care.* 2005 Nov; 28(11): 2,607-2,612.

PubMed ID: 16249527

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine the effects on blood pressure and heart rate of consuming controlled isoenergic high-carbohydrate and high-monounsaturated fat diets in subjects with type 2 diabetes. The effects of these diets on glucose and lipid metabolism were published previously.

Inclusion Criteria:

Not described.

Exclusion Criteria:

Not described.

Description of Study Protocol:

Design

A four-center, randomized, cross-over study in which subjects followed each intervention diet for six weeks, with a one-week washout period between interventions. A sub-sample of subjects followed the second diet they received for an additional eight weeks.

Dietary Intake/Dietary Assessment Methodology

Subjects were provided with all food consumed during the study. To monitor compliance, subjects were instructed to bring back any unconsumed food and were interview by dietitians.

Intervention

- Daily energy intake needed for weight maintenance was estimated for each subject by

multiplying the calculated basal energy expenditure by an activity factor
- Each patient then received each of the two isoenergic study diets for six weeks each, with a median of seven days between the two-diet period
- High-carbohydrate diet: 55% energy as carbohydrate and 30% as fat
- High-monounsaturated diet: 45% energy as fat and 40% as carbohydrate
- The saturated and polyunsaturated fats (10% each), protein (15% of energy), cholesterol (120mg per 1,000kcal) and sucrose (10% of total energy) contents of the study diets were matched. Fiber content was proportional to the carbohydrate content of each diet (11g per 1,000kcal for the high-monounsaturated fat diet and 15g per 1,000kcal for the high-carbohydrate diet)
- To assess the longer-term effects of diets, all patients were invited to consume the second diet for an additional eight weeks (extension phase) without interruption, and 21 subjects chose to do so.

Statistical Analysis

- Repeated measures ANOVA was used to assess the impact of the study diets, in the order in which patients received the diets and the site of study participation on blood pressure and heart for six weeks in 41 patients and for 14 weeks in 21 patients
- Least-square means contrasts were used to analyze the differences among the three phases (phases one, two and extension) when ANOVA revealed significant diet effects
- The effects of possible confounding factors, such as age, sex and weight, were also evaluated using repeated-measures ANOVA and covariance models.

Data Collection Summary:

Timing of Measurements

During the last three days of each diet phase, the subjects were admitted to the inpatient metabolic unit, where blood pressure and heart rated were measured daily. The mean of the measures taken during the last three days of each phase were averaged.

Dependent Variables

Blood pressure and heart rate were measured by study personnel in the left arm on the last three days of each diet phase, and weekly during all remaining weeks on an outpatient basis after a five-minute rest.

Independent Variables

Dietary intake: All food consumed during the study was provided to subjects from a metabolic kitchen. To monitor compliance, subjects were instructed to bring back any unconsumed food and were interview by dietitians.

Control Variables

- Age
- Sex
- Weight.

Description of Actual Data Sample:

- *Initial N:* 42 (33 men, nine women)
- *Attrition (final N):* 41 (one subjects was dropped due to lack of blood pressure data). Also, N=21 subject participated in the extension phase of the study (eight continued on the high-monounsaturated fat diet and 13 continued on the high-carbohydrate diet)
- *Age:* 58±10 years
- *Ethnicity:* 31 patients were white, six were African American, four were Hispanic and one was Asian
- *Anthropometrics:*
  - BMI=28.1±2.9kg/m^2
  - Systolic blood pressure = 134±18mmHg
  - Diastolic blood pressure = 80±9mmHg
  - Heart = 75±8 beats per minute
- *Location:*
  - Stanford, CA
  - Dallas, TX
  - Minneapolis, MN; San Diego, CA.

Summary of Results:

Blood Pressure and Heart in Subjects from Phase One and Two (N=41)

- During the last three days of phases one and two, energy intake and body weight did not differ between the two diets
- The order in which subjects received the diets did not affect the results
- After six weeks of the high-carbohydrate and high-monounsaturated fat diets, no differences were observed in systolic blood pressure or diastolic blood pressure
- Heart rate was slightly higher on the high-carbohydrate (73±8 beats per minute) compared to the high-monounsaturated fat (71±8) diet (P=0.06).

Blood Pressure and Heart Rate on the Two Diets in Patients who Participated in the Extension Phase (N=21)

- There were no differences in energy intake or body weight during the last three days of phases one, two or extension in the 13 patients who received the high-carbohydrate diet for 14 weeks or in the eight patients who received the high-monounsaturated fat diet for 14 weeks
- There was a significant diet effect for diastolic blood pressure (7mmHg, P=0.003) and heart rate (seven to eight beats per minute, P=0.03); both were significantly higher on the high-carbohydrate diet at 14 weeks compared to the high-monounsaturated and the high-carbohydrate diet at six weeks
- There was no significant diet effect for systolic blood pressure; however, it was higher (6mmHg, P=0.04) on the high-carbohydrate diet at 14 weeks than on the high-monounsaturated fat diet at six weeks
- Heart rate was significantly lower on the high-monounsaturated fat diet at 14 weeks (seven beats per minute, P=0.02) and six weeks (six beats per minute, P=0.05) than on the high-carbohydrate diet at six weeks.

Other Findings

- Compliance with the study protocol was excellent

- The sites at which the patients were studied did not have differing results, so combined results from all four centers were reported
- Subjects who were taking blood pressure-lowering medication had similar results to subjects who weren't taking medication, so results were combined.

Author Conclusion:

- The exchange of carbohydrates with monounsaturated fats did not affect blood pressure at six weeks, but did have a modest impact on this measure in the longer-term (14 weeks)
- In subjects who received the high-monounsaturated diet for six weeks and the high-carbohydrate diet for 14 weeks, blood pressure was significantly higher on the latter diet
- In subjects who received the high-carbohydrate diet for six weeks, and the high-monounsaturated diet for 14 weeks, blood pressure was higher on the former diet, but the difference not reach statistical significance, possibly due to small sample size.

Reviewer Comments:

- *This study used small sample sizes for phase one and two, and smaller sample sizes for the phase two extension*
- *It is possible that six weeks was not long enough to see results in phases one and two of the study, making it difficult to draw conclusions from this study*
- *Subject characteristics were not fully described, particularly for the subjects who participated in the phase two extension.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes

1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	No
2.2.	Were criteria applied equally to all study groups?	No
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	No
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	???
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	???
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???

4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	No
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	No
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	No
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes

7.5.	Was the measurement of effect at an appropriate level of precision?	No
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes